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In The
Supreme Court of the United States

WARNER-LAMBERT COMPANY and PFIZER INC.,

Petitioners,

v.

MARY ROSE WAKEFIELD, INDIVIDUALLY, AS PERSONAL REPRESENTATIVE, TRUSTEE, EXECUTOR OF THE ESTATE OF MICHAEL HOLMES WAKEFIELD AND MARY LOUISE WAKEFIELD,

Respondent.

On Petition For Writ Of Certiorari To The Oklahoma Court Of Civil Appeals

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the $10 million punitive damage award was excessive and arbitrary, in violation of the Due Process clause of the Fourteenth Amendment, because it was calculated from world-wide gross sales of an FDA-approved prescription drug, in conflict with *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003), and *BMW of North America v. Gore*, 517 U.S. 559, 573 (1996).

2. Whether the $10 million punitive damage award, nearly seven times the $1.55 million compensatory damage award, was grossly excessive under the standard in *State Farm*, 538 U.S. at 425, that "an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety," and that where, as here, "compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee."

RULE 29.6 STATEMENT

Petitioner Warner-Lambert Company is a wholly-owned subsidiary of petitioner Pfizer Inc. Pfizer Inc. has no parent corporation. No publicly held company owns 10% or more of the stock of Pfizer Inc.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Warner-Lambert Company ("Warner-Lambert") and Pfizer Inc. ("Pfizer") respectfully petition for a writ of certiorari to review the judgment of the Oklahoma Court of Civil Appeals in this case, which affirmed a judgment following a jury verdict of $1.55 million compensatory damages and $10 million punitive damages against petitioners.

OPINION BELOW

The unpublished opinion of the Oklahoma Court of Civil Appeals, filed on July 20, 2004, is reprinted in the attached appendix ("App.") at 1-19.

STATEMENT OF JURISDICTION

The Supreme Court of Oklahoma denied petitioners' timely petition for certiorari on November 1, 2004, without opinion. App. 20. Petitioners invoke this Court's jurisdiction under 28 U.S.C. § 1257(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fourteenth Amendment to the U.S. Constitution, § 1, and the Oklahoma punitive damages statute, 23 OKLA. STAT. § 9.1, are reprinted at App. 22-25.

STATEMENT OF THE CASE

This product liability action arises from the treatment of diabetes with the prescription drug Rezulin, which was manufactured by defendant Warner-Lambert. Rezulin was found to be safe and effective and was approved for sale by the U.S. Food and Drug Administration ("FDA"). The FDA has the statutory responsibility to approve and regulate prescription drugs, and to weigh their risks against the benefits of effective treatment for diseases such as diabetes, which can be life-threatening. *See* 21 U.S.C. § 355(d). After Rezulin was in use for about three years, it was withdrawn from the market when two next-generation drugs of the same type were introduced. Each of these diabetes drugs, like hundreds of other prescription drugs, has a potential for liver damage in some patients, as their FDA-approved warnings state.

As is commonplace in today's tort environment, following the withdrawal of Rezulin thousands of lawsuits were filed. While there were some plaintiffs' verdicts, such as this case, there were also a number of defendants' verdicts as well as numerous dismissals as a matter of law. While Rezulin was in use, the FDA repeatedly found that its benefits for diabetics outweighed its risks; the vast majority of Rezulin patients had no liver side-effects. And in the trial of this case, every treating physician testified to Rezulin's safety and effectiveness.

Despite these facts, the trial court below allowed plaintiffs' counsel to argue that the jury should calculate punitive damages based on the alleged profit on *worldwide* Rezulin sales during the five-week period when Mr. Wakefield was treated with samples of the drug. The court refused instructions, based on principles set forth in *BMW*

of North America v. Gore, 517 U.S. 559, 572-73 (1996), and reiterated in *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422 (2003), to limit the jury's focus to Oklahoma transactions. The huge punitive damage verdict that resulted, if allowed to stand, in effect allows one jury in one state court lawsuit to override FDA decisions and to regulate the legality of prescription drug sales nationwide and, indeed, worldwide. Thus, the Oklahoma courts' blatant rejection of this Court's limitations on punitive damages affects national health care policy, raising issues that extend far beyond those decided in *BMW* and *State Farm*.

The FDA-approved product at issue. Rezulin was a breakthrough diabetes medication that controlled blood sugar levels when existing drugs could not. As one senior FDA official told an Advisory Committee before Rezulin was approved: "we do not have effective therapy, drug therapy, for Type II diabetes presently, and we urgently need new therapies for this condition." R.3825, DX-0932 at 16.[1] In January 1997 the FDA approved Rezulin after finding that it was "safe and effective for use" and that its benefits outweighed its risks. R.3789, Tr. 958-59; R.3791, Tr. 1248; R.3792, Tr. 1297, 1320-24, 1330-34. The FDA's Director of the Division of Metabolic and Endocrine Drug Products stated that Rezulin "was shown to have distinct benefits in respect to improved glycemic [blood sugar] control and/or insulin reduction in an impressive percentage of patients who were inadequately controlled with insulin." R.3815, Tr. 2912. Thereafter, the FDA approved Rezulin for two additional uses, following further evaluation of its

[1] "R." refers to the record in the Oklahoma Court of Civil Appeals.

benefits as well as the risk of liver injury associated with the drug. R.3792, Tr. 1337. In March 1999, an FDA advisory committee with a "distinguished panel of experts" considered the actual performance of Rezulin based on millions of uses and adverse event reports that included liver injury in some patients. The FDA committee voted to approve Rezulin for continued use in combination with insulin or sulfonylurea drugs. R.3793, Tr. 1400-01; R.3794, Tr. 1497-98. Rezulin was withdrawn in March 2000 after two second-generation drugs of the same type (Actos and Avandia) were introduced. R.3819, Tr. 3043. Those drugs also have been associated with liver injuries at somewhat lower levels, and their labels recommend regular liver function tests. R.3794, Tr. 1469-70; R.3814, Tr. 2749-50.

Mr. Wakefield. Plaintiff's decedent, Michael Wakefield, had life-threatening diabetes, and was treated with Rezulin for about five weeks beginning in February 1999. R.3797, Tr. 1768-69; R.3798, Tr. 1846-48, 1882. Prior to his Rezulin treatment, Mr. Wakefield had been hospitalized five times for diabetic ketoacidosis, a potentially fatal blood condition. R.3808, Tr. 2259, 2263-65; R.3810, 2274. During his last hospitalization for ketoacidosis on March 8, 1999, he was given an antibiotic, Rocephin, made by a company not involved in this case. R.3798, Tr. 1852-53, 1887; R.3797, Tr. 1771, 1786. He then developed hemolytic anemia (R.3798, Tr. 1856), from which he died on March 15, 1999. ***Every*** treating physician concluded, and a specific blood test confirmed, that Mr. Wakefield's death resulted from hemolytic anemia caused by Rocephin. R.3797, Tr. 1793-95; R.3798, Tr. 1903; R.3804, Tr. 2060-61. The Rocephin product label expressly lists hemolytic anemia as a reported adverse reaction. R.3796, Tr. 1756-57. The treating physicians unanimously concluded that

Mr. Wakefield's death was not caused by Rezulin. R.3797, Tr. 1795; R.3798, Tr. 1903; R.3804, Tr. 2033-34.

It was undisputed that all diabetes drugs have risks, which do not preclude their use in light of the life-threatening nature of the disease. The FDA-approved label in effect when Mr. Wakefield took Rezulin had a black-box warning about possible "idiosyncratic hepatocellular [liver] injury," which could result in "hepatic [liver] failure leading to death or liver transplant." R.3825, DX 7. Mr. Wakefield's prescribing physician, Dr. Simon Levit, testified that he was "very aware that the drug had potential side effects regarding the liver," and knew that he "needed to watch for hepatic dysfunction" and did so. R.3798, Tr. 1844-45, 1867.

Despite the risks, every physician involved in this case who had prescribed Rezulin (except plaintiffs' paid expert, Dr. Julie, who was not a diabetes specialist) testified to its overall safety and effectiveness. None observed any serious liver injury to their patients who took Rezulin. For example, Dr. Levit testified that Rezulin was needed to supplement other treatments because it "had another way of working," and that he "felt the drug had definite usage and definite indications and I wanted to use it." R.3798, Tr. 1882, 1884. Dr. Hanson, Mr. Wakefield's endocrinologist, "found it to be an excellent drug," with "really outstanding" effectiveness, which he prescribed for "hundreds of patients." R.3797, Tr. 1779; R.3798, Tr. 1836. *See also* R.3815, Tr. 2889; R.3817, Tr. 3025, 3034.

Proceedings below. The case went to trial against Warner-Lambert and Pfizer in March 2002 before a jury in the District Court of Tulsa County, Oklahoma. Plaintiff had originally named Dr. Levit as a defendant as a ploy to

defeat removal to a federal court (which would have applied the requirements of *BMW* and *State Farm*); plaintiff voluntarily dismissed him on the first scheduled day of trial. R.2896.

After the first phase of the trial, in which the jury awarded $1.55 million in compensatory damages, the case proceeded to a punitive damages phase. The court denied defendants' request to charge the jury that it may not punish defendant "for any impact its conduct may have had on individuals in other states" (R.3231, Nos. 41; R.3823, Tr. 3393-94), based on *BMW*, 517 U.S. at 572-73 (*State Farm* had not yet been decided). The court also overruled objections that punishment of defendants based on out-of-state conduct is unconstitutional, and that there was inadequate evidence from which the jury could determine punitive damages under 23 OKLA. STAT. § 9.1(C), based on "the increased financial benefit derived by the defendant as a direct result of the conduct causing the injury to the plaintiff and other persons or entities." R.3823, Tr. 3387-90. Instead, the court gave the jury a perfunctory instruction essentially in the words of the Oklahoma statute. *Id.* at 3401-02. The jury was not told by the trial court of any geographic or substantive limitations which they could apply to properly compute financial benefit from the conduct that caused injury to the plaintiff. Nor did the court define who the "other persons or entities" were, for whom financial benefit from harm could be calculated, or the geographic location of such other persons or entities.

Plaintiffs' counsel then asked the jury to award punitive damages based on Warner-Lambert's alleged worldwide profit on Rezulin, which she asserted was $21 million for the five-week period during which Mr. Wakefield was treated

with Rezulin and "$600 million, which is the three-year profit that this company made off this drug." *Id.* at 3410. While the annual gross sales were taken from Warner-Lambert's annual reports, there was no evidence of actual profits. Plaintiff's counsel told the jury that Warner-Lambert's profit on Rezulin was 30% (*id.*), but that was simply what the company intended to "strive" for; there was no proof of the amount of actual profits. R.3806, Tr. 2090. Plaintiff's counsel did not present any evidence that selling Rezulin during this five-week period was illegal, and could not do so given the FDA approval. Nor did plaintiff show that other people in Oklahoma had been injured by the drug. To the contrary, the treating physicians, who were local practitioners, testified to the drug's safety and effectiveness.

Defendants' argument that the punitive damage award is unconstitutional was amply preserved. The trial court overruled defendants' objections that common law, statutory and federal constitutional requirements for punitive damages were not satisfied. R.3823, Tr. 3386-90, 3399-3400. Defendants then raised the constitutional issue in their Motion for Judgment Notwithstanding the Verdict, New Trial, Remittur, and to Correct, Open, Modify or Vacate the Judgment (R.3294-3307), which was overruled on March 10, 2003, without opinion. R.3740-41. Defendants raised the constitutional issue again in their appellate brief (at 26-29) and in their petition for certiorari to the Supreme Court of Oklahoma (at 8-10).

The Oklahoma Court of Civil Appeals affirmed the judgment in its entirety. Specifically, the court endorsed the calculation of punitive damages based on financial benefit measured by profit from "world-wide gross sales." App. 17. The court also accepted plaintiffs' assertion that

there was testimony to support a 30% profit margin when there was no such proof. As discussed below, the court simply failed to address the conflict between the calculation of the punitive damage award and the constitutional requirements for considering out-of-state conduct specified by the Supreme Court in *BMW* and *State Farm*. App. 17-19. Moreover, the gross errors underlying the punitive damage award were part of a larger pattern of error in other aspects of the trial, and the appellate review was so divorced from the controlling case law and the record, as to make the entire proceeding an outrageous miscarriage of justice against two out-of state defendants.

Plaintiff's evidence of causation rested entirely on the testimony of plaintiff's paid expert Dr. Julie, a Maryland physician who offered no testimony about the effect of Rezulin on Oklahoma patients. R.3795, Tr. 1625. Dr. Julie opined that Rezulin caused Mr. Wakefield's hemolytic anemia, but could not cite any study finding that Rezulin can cause hemolytic anemia. *Id.* at 1648-49. Two treating physicians also testified that there was no indication of any liver injury. R.3797, Tr. 1780-83; R.3798, Tr. 1860. Indeed, even at his death Mr. Wakefield's liver was in such good condition that it was transplantable. R.3815, Tr. 2975; R.3819, Tr. 3066. Yet, the Oklahoma Court of Civil Appeals asserted (without citation) that Mr. Wakefield had a liver injury when he was hospitalized. App. 2. Defendants challenged the reliability of Dr. Julie's opinions, but the trial court allowed him to testify without making any findings or applying any legal standard. The court simply "assume[d]," based on the word of plaintiff's counsel, that Dr. Julie "must have some basis for his opinion." R.3780, Tr. 36. The Court of Civil Appeals affirmed, without applying any of the factors in *Daubert v. Merrell Dow*

Pharm., 509 U.S. 579, 592-93 (1993), which Oklahoma has adopted. App. 12.

The trial court denied defendants' request that no jury instruction be given on strict liability or, alternatively, to allow the jury to decide whether Rezulin was unavoidably unsafe under Comment k to the RESTATEMENT (SECOND) OF TORTS, § 402A (1965), particularly in light of its FDA approval (R.3820-22, Tr. 3213-14, 3235-36 3376-78), despite Oklahoma case law stating that under Comment k all prescription drugs are "unavoidably unsafe" and there is no liability if an adequate (non-negligent) warning is given. The trial court also refused instructions distinguishing a condition from a cause, which allowed plaintiff's counsel to argue that if Mr. Wakefield even had nausea as a result of Rezulin, went to the hospital, and died there from Rocephin, defendants should be liable. R.3822, Tr. 3365-66. It is thus apparent that, in contrast to *State Farm*, the case for liability was weak, particularly given the sharp dispute on the medical issues between plaintiffs' paid expert and the treating physicians. A $10 million punitive damage judgment that might have been predicated on nausea as a side-effect to an otherwise effective drug is beyond the pale.

REASONS FOR GRANTING THE WRIT

The Court is called upon here not merely to address the Oklahoma courts' flagrant disobedience of this Court's decisions in *BMW of North America v. Gore*, 517 U.S. 559 (1996), and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003). In addition, for the first time, the Court is asked to consider the extent to which the constitutional

protections in those cases limit a state's power to impose punitive damages in a product liability action against out-of-state defendants when the only basis for calculating punitive damages was worldwide sales of the product, which were authorized in the United States by the FDA and in other countries by their regulatory agencies. The importance of correctly applying constitutional protections in these circumstances is demonstrated by the adverse consequences for health care of enabling one state, through its juries, to effectively regulate the out-of-state sale of drugs which, in the FDA's judgment, have benefits that outweigh their possible side-effects. The impact of such state regulation through jury trials and punitive damage awards can be exacerbated many times over by numerous such lawsuits and punitive damage awards, both against these defendants and in the plethora of product liability actions involving pharmaceutical manufacturers around the country.[2]

In granting certiorari to review the legality of a state libel judgment, the Court observed: "Whether or not a newspaper can survive a succession of such judgments, the pall of fear and timidity imposed upon those who would give voice to public criticism is an atmosphere in which the

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[2] Recent punitive damage awards in drug and medical product liability cases include *Coffey v. Wyeth*, No. E-167334 (Dist. Ct. Jefferson Co. Tex. Apr. 7, 2004) ($900 million punitive damages in Pondimin case); *Arrow Int'l, Inc. v. Sparks*, 98 S.W.3d 48 (Ark. Ct. App. 2003) ($4 million punitive damages in medical device case); *McClain v. Metabolife Int'l, Inc.*, 259 F. Supp. 2d 1225 (N.D. Ala. 2002) ($3.25 million punitive damages in cases involving Metabolife); *Axen v. American Home Prod. Corp.*, 974 P.2d 224 (Or. App. 1999) ($20 million punitive damages in case involving Cordarone); *Lovett v. Wyeth Ayerst*, No. 97-00665 (Dist. Ct. Van Zandt Co. Tex. Aug. 1999) ($20 million punitive damages in Phen-Fen case).

First Amendment freedoms cannot survive." *New York Times Co. v. Sullivan*, 376 U.S. 254, 278 (1964).[3] By a parity of reasoning, development of new drugs by pharmaceutical companies will be threatened by "the pall of fear and timidity" that would be imposed by a succession of punitive damage judgments calculated on the basis of FDA-approved national or worldwide sales of innovative prescription drugs, which have risks but nevertheless save many lives. If the decision below is allowed to stand, the due process protections this Court has imposed on punitive damage awards will be nullified, with adverse consequences for medical progress and health care.

This Court also has stated that: "We are concerned with federal issues and a contention that a state court disregarded a federal constitutional ruling of the Court." *Limbach v. Hooven & Allison Co.*, 466 U.S. 353, 362 (1984). Following that principle, the Court has repeatedly

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[3] The Court also noted that: "The Times states that four other libel suits based on the advertisement have been filed against it," that there was another large verdict, and that damages sought in three other cases total $2 million." *See id.* at n.18. In addition to thousands of suits filed against these defendants regarding Rezulin, *see, e.g., In re Rezulin Prod. Liab. Litig.*, 210 F.R.D. 61 (S.D.N.Y. 2002), there are numerous multi-district litigation proceedings involving pharmaceuticals against other manufacturers, including *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prod. Liab. Lit.*, MDL 1203 (E.D. Pa.); *In re Rezulin Prod. Liab. Lit.*, MDL 1348 (S.D.N.Y); *In re Propulsid Prod. Liab. Lit.*, MDL 1355 (E.D. La.); *In re Baycol Prod. Liab. Lit.*, MDL 1431 (D. Minn.); *In re Serzone Prod. Liab. Lit.*, MDL 1477 (S.D. W. Va.); *In re Meridia Prod. Liab. Lit.*, MDL 1481 (N.D. Ohio); *In re Paxil Prod. Liab. Lit.*, MDL 1574 (C.D. Cal.); *In re Zyprexa Prod. Liab. Lit.*, MDL 1596 (E.D.N.Y.); *In re Accutane Prod. Liab. Lit.*, MDL 1626 (M.D. Fla.), and many un-removable state court actions.

granted certiorari in cases where, as here, a state court decision conflicts with Supreme Court case law.[4]

The Oklahoma Court of Civil Appeals failed to remedy the constitutional infirmities in the trial court's punitive damage award and related proceedings. Far from applying "[e]xacting appellate review" to ensure that "an award of punitive damages is based upon an 'application of law, rather than a decisionmaker's caprice,'" as required by this Court (*State Farm*, 538 U.S. at 418), the Court of Civil Appeals simply ignored the constitutional issues and standards set forth in *State Farm* and *BMW*, which preclude punitive damage calculations based on out-of-state or nationwide transactions, whether the court awarding the damages determines that such conduct was legal or illegal. The result was an egregious conflict with this Court's rulings. Summary reversal under Supreme Court Rule 16(1) is therefore warranted.

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[4] *See, e.g., Lilly v. Virginia*, 527 U.S. 116, 123 (1999) ("Our concern that this decision represented a significant departure from our Confrontation Clause jurisprudence prompted us to grant certiorari"); *Oregon v. Mathiason*, 429 U.S. 492, 492-93 (1977) (certiorari granted and judgment reversed because lower court "read *Miranda* too broadly"); *City of Pittsburgh v. Alco Parking Corp.*, 417 U.S. 369, 371-72 (1974) ("Because the decision [of the Pennsylvania Supreme Court] appeared to be in conflict with the applicable decisions of this Court, we granted certiorari"); *Willam E. Arnold Co. v. Carpenters Dist. Council of Jacksonville and Vicinity*, 417 U.S. 12, 14 (1974) ("We granted certiorari to decide whether the holding of the Florida Supreme Court was consistent with decisions of this Court"); *Wilson v. Schnettler*, 365 U.S. 381, 383 (1961) ("To consider petitioner's claim that the judgment is repugnant to controlling rules and decisions of this Court, we granted certiorari").

I. PUNITIVE DAMAGES WERE UNCONSTITUTIONALLY BASED ON THE OUT-OF-STATE SALES OF AN FDA-APPROVED PRESCRIPTION DRUG

World-wide sales as the sole basis for the amount of the punitive damage award. The punitive award was based on 23 OKLA. STAT. § 9.1(C), which provides that the jury may calculate punitive damages in an amount not exceeding the greatest of (a) $500,000, (b) twice the amount of actual damages awarded, or "the increased financial benefit derived by the defendant as a direct result of the conduct causing the injury to the plaintiff and other persons or entities." R.3823, Tr. 3402. Because the award was more than allowed under the first two options, the only basis for the calculation was the increased financial benefit. The Court of Civil Appeals held that "evidence of the dollar amount of world-wide gross sales of Rezulin – $48 million per month," and "expert testimony" – which in fact is non-existent – "that [Warner-Lambert's] profit margin on Rezulin sales was thirty percent," provided "evidentiary support for the award of punitive damages." App. 17. This was the only "evidentiary support" that the court identified for the award, and the only basis on which to calculate punitive damages that plaintiff's counsel argued to the jury in summation during the punitive damages phase of the trial. Specifically, plaintiff's counsel asserted that Warner-Lambert's profit on Rezulin during the 1997-99 period was "$600 million," and that the profit "over the five weeks that Michael Wakefield took the drug is $21 million." R.3823, Tr. 3410.

In addition to telling the jury to calculate the amount of punitive damages solely from world-wide sales, plaintiff's counsel argued that punitive damages should be

awarded because Warner-Lambert "brought this drug to market" – again referring to the fact that it sold the product nationally. *Id.* at 3403, 3405, 3407. This followed other argument and evidence regarding Warner-Lambert's out-of-state conduct, including allegations about a small percentage of adverse liver events among the nearly two million Rezulin patients nationwide. *See, e.g.*, R.3789, Tr. 917; R.3821, Tr. 3288; R.3823, Tr. 3405-06.

BMW's and State Farm's limitation to in-state transactions. In *BMW*, 517 U.S. at 574, this Court ruled, in the context of a lawsuit involving a nationally distributed product, that under the U.S. Constitution "the scope of the interest in punishment and deterrence that [a state] court may appropriately consider is properly limited" to the interests of that State's citizens, "rather than those of the entire Nation." Before the case reached this Court, the Alabama Supreme Court "found that the jury improperly computed the amount of punitive damages by multiplying Dr. Gore's compensatory damages by the number of similar sales in other jurisdictions," and accordingly ordered a remittitur. *Id.* at 567. There was no evidence that the defendant's out-of-state conduct was unlawful, as in this case where the nationwide sale of Rezulin was authorized by FDA. This Court concluded that the "Alabama Supreme Court, therefore, properly eschewed reliance on BMW's out of state conduct . . . and based its remitted award solely on conduct that occurred within Alabama." *Id.* at 573. That is precisely what the Oklahoma appellate courts refused to do here.

Moreover, in *BMW* the Court found that the Alabama Supreme Court had not gone far enough. Thus, a State may not "punish [a defendant] for conduct that was lawful where it occurred and that had no impact on [that State]

or its residents. Nor may [a State] impose sanctions on [a defendant] in order to deter conduct that is lawful in other jurisdictions." *Id.* Thereafter, in *State Farm* the Court made it clear that punitive damages may not be imposed to punish out-of-state conduct *regardless* whether that conduct would be considered lawful or unlawful where it occurred:

> "A State cannot punish a defendant for conduct that may have been lawful where it occurred. . . . *Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction.* . . . [E]ach State alone can determine what measure of punishment, if any, to impose on a defendant who acts within its jurisdiction."

538 U.S. at 421-22 (emphasis added). *Accord, Continental Trend Resources, Inc. v. OXY USA Inc.*, 101 F.3d 634, 637 (10th Cir. 1996) ("[A]ny penalty must be supported by Oklahoma's 'interest in protecting its own consumers and its own economy.' . . . [W]e read the opinion [in *BMW*] to prohibit reliance upon inhibiting unlawful conduct in other states"). Thus, only the State where the conduct occurred can determine if it was lawful there. And taking the Court's reasoning one step further, only the FDA, and not a jury or court in a single case in Oklahoma, can determine if a prescription drug can lawfully be sold throughout the nation.

Unconstitutionality of the Oklahoma punitive damages statute as applied. The punitive damage instructions were based on 23 OKLA. STAT. § 9.1(C), which authorized punitive damages based on the "increased financial benefit" to the defendant occurring "as a direct result of the conduct

that caused injury to the plaintiff and other persons and entities." On its face, the statute fails to provide juries and courts with standards sufficient to constrain them from making awards calculated on the basis of out-of-state transactions. Thus, the statute fails to limit the "other persons and entities" who may have been caused injury to people in Oklahoma. Moreover, the Oklahoma courts construed the statute to authorize punitive damages based on conduct that did ***not*** cause injury, *i.e.*, the sale of Rezulin to millions of patients who were treated effectively, without injury. If the size of the product line is all that matters, then there are no effective limits on punitive damages in any case involving a nationally marketed, standard product. The statute as interpreted and applied here thus squarely conflicts with *BMW* and *State Farm*, which preclude a punitive damage award based on the general sale of the drug throughout the world.

The erroneous jury instructions. In *State Farm*, 538 U.S. at 422, the Court, citing *BMW*, directed that: "A jury must be instructed . . . that it may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred." Defendants requested instructions, based on *BMW*, that the jury "may not punish defendant for any adverse impact its conduct may have had on anyone other than Mr. Wakefield and the plaintiff," or "for any impact its conduct may have had on individuals in other states." R.3230-31, Nos. 40-41. The trial court denied both instructions. R.3823, Tr. 3393-94. As this Court pointed out in *State Farm*, 538 U.S. at 418: "Vague instructions, or those that merely inform the jury to avoid 'passion or prejudice,' do little to aid the decisionmaker in its task of assigning appropriate weight to evidence that is relevant and evidence that is tangential or

only inflammatory." Here, the trial court's cursory punitive damage charge did not contain even such vague admonitions, let alone the explicit instruction regarding out-of-state conduct required by *BMW*. R.3823, Tr. 3401-02. *Accord, White v. Ford Motor Co.*, 312 F.3d 998, 1020 (9th Cir. 2002) (reversing punitive damage judgment in product liability case; trial court's "refusal to limit the jury to consideration of Nevada's interests, combined with the plaintiffs' lawyers exhortations to let the decision resonate 'across the country,'" resulted in "'a due process violation of the most basic sort' when [the jury] arrived at its punitive damages award").

The perfunctory appellate decision. As this Court stated in *State Farm*, 538 U.S. at 418: "Exacting appellate review ensures that an award of punitive damages is based upon an 'application of law, rather than a decision-maker's caprice.'" (Quoting *BMW*, 517 U.S. at 587.) Here, in response to defendants' argument based on *BMW* and *State Farm*, the Oklahoma Court of Civil Appeals merely stated, without explanation, that "[t]he punitive damages award in this case neither reflects a grossly excessive award, nor attempts to sanction Manufacturing Defendants for conduct legal in other states." App. 18. But because the only measure of punitive damages was *worldwide* Rezulin sales, which the Oklahoma court explicitly recognized earlier in its opinion, defendants plainly were sanctioned for conduct "in other states" and, indeed, other countries. Moreover, under *State Farm*, 538 U.S. at 421, punitive damages may not be awarded to punish out-of-state conduct whether it is lawful or unlawful, so the Oklahoma court mis-stated this Court's test. What is more, the court below did not identify any evidence that these worldwide sales were all "illegal"; there is

no such evidence in the record; and the court could not simply assume that there was anything "illegal" about those sales, particularly where the drug was FDA-approved. *Cf. Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424, 442 (2001) (in assessing punitive damages, "it would be unrealistic to assume that all of Cooper's sales of the [product] would have been attributable to its misconduct in using a photograph of a modified [product made by Leatherman] in its initial advertising materials").[5]

Absence of any basis for illegality of worldwide sales. Rezulin was sold in the United States pursuant to FDA approval, and also was sold in other countries whose public health agencies approved the drug. The sale of Rezulin was therefore legal. Moreover, worldwide Rezulin sales included sales to the vast majority of patients who benefitted greatly from the drug and had no ill effects. *See, e.g.*, Dr. Hanson's testimony that Rezulin was "an excellent drug," with "really outstanding" effectiveness, which he prescribed for "hundreds of patients" (R.3797, Tr. 1779; R.3798, Tr. 1836); *In re Rezulin Prod. Liab. Lit.*, 210 F.R.D. 61, 66 n.37 (S.D.N.Y. 2002) (even plaintiffs' experts admit that "Rezulin was effective for 95 percent of the patients who ingested it"). Such sales plainly were not "illegal," and cannot be the basis of a punitive damage award.

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[5] If plaintiffs contend, in opposition, that illegality flows from Warner-Lambert's claimed misrepresentations to the FDA in obtaining approval for Rezulin, that argument would be impermissible under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001), which held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law."

The unfairness of calculating punitive damages on the totality of out-of-state sales also is illustrated by the fact that, while there have been some other plaintiffs' verdicts in product liability actions involving Rezulin, a number of juries in other states have returned defense verdicts in such cases.[6] *See BMW*, 517 U.S. at 572 n.17 ("State power may be exercised as much by a jury's application of a state rule of law in a civil lawsuit as by a statute."). There also have been hundreds of cases from around the country dismissed by the federal multi-district Rezulin litigation court (*see, e.g., In re Rezulin Prod. Liab. Litig.*, 2004 WL 1161248 (S.D.N.Y. May 25, 2004)), and more than 20 state court dismissals. Thus, there is no basis to find that Rezulin sales in those states, even sales to the plaintiffs who filed suit in those other states, were "illegal."

Lack of fair notice that worldwide sales can be a basis for punitive damages. In *BMW*, 517 U.S. at 574, this Court explained that due process does not permit out-of-state transactions to be the basis for calculating punitive damages, because: "Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice . . . of the severity of the penalty that a State may impose." The *BMW* Court further observed that: "The fact that BMW is a large corporation rather than an impecunious individual does not diminish its entitlement to fair notice of the demands that the several States impose on the conduct of its business. Indeed, its status as

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[6] *Cervantes v. Warner-Lambert Co.*, No. 4122 (Cal. Super. Ct. L.A. Co., May 27, 2004); *Brown v. Warner-Lambert Co.*, No. 348-181927-00 (Dist. Ct. Tarrant Co. Tex. Feb. 18, 2003) (appeal pending); *Shaw v. Warner-Lambert*, No. 209074 (Cir. Ct. Montgomery Co. Md., Feb. 2, 2002); *Mercado v. Warner-Lambert Co.*, No. 2000-42692 (Dist. Ct. Harris Co. Tex. Dec. 17, 2001).

an active participant in the national economy implicates the federal interest in preventing individual States from imposing undue burdens on interstate commerce." *Id.* at 585. Here, particularly in light of *BMW*, these non-resident defendants could not conceivably have predicted that punitive damages would be calculated based on worldwide sales and awarded for a claim on behalf of a single person treated with this FDA-approved drug in Oklahoma, whose FDA-approved warning stated that some patients had experienced serious side effects including liver disease.

The absence of "nexus to specific harm" under State Farm. Nor do world-wide sales have "a nexus to the specific harm suffered by the plaintiff," as required by *State Farm*, 538 U.S. at 422, or an "impact on [that State] or its residents," as required by *BMW*, 517 U.S. at 573. Courts may not award punitive damages "to punish and deter conduct that bore no relation to the [plaintiff's] harm." *State Farm*, 538 U.S. at 422. "Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis." *Id.* at 423.

The Oklahoma appellate court acknowledged defendants' argument that there is an "insufficient nexus" between the worldwide sales of Rezulin on which the punitive damage award was based and the actual harm to the plaintiff (App. 17), but never responded to it. The court did not identify any nexus between (1) Warner-Lambert's worldwide sales of Rezulin during the time that Mr. Wakefield took the medication and (2) any harm to Mr. Wakefield, and there is no such nexus in the record. In effect, the court below "adjudicate[d] the merits" of "hypothetical claims"

against Warner-Lambert by everyone who purchased and took Rezulin worldwide, including people whose diabetes was controlled by the drug and had no side-effects, and those who filed suit and were found to have no claim. *State Farm*, 538 U.S. at 423. Under this Court's holdings, that is impermissible. Sales of the medication to diabetics who benefitted from it and were not injured – the vast majority of patients who were treated with it – provide no basis for "deterrence" or "retribution," the purpose of punitive damages, and therefore cannot be a basis for a punitive award. *Id.* at 416.

Arbitrariness of the award. In *State Farm*, this Court emphasized that punitive damages may not be awarded arbitrarily. *See, e.g., id.* at 409 ("The Due Process Clause prohibits the imposition of grossly excessive or arbitrary punishments on a tortfeasor"; "punitive damages pose an acute danger of arbitrary deprivation of property"); *id.* at 416-17 (the constitutional concern related to "'arbitrary coercion'"); *id.* at 418 ("'A State can have no legitimate interest in deliberately making the law so arbitrary that citizens will be unable to avoid punishment based solely upon bias or whim'"); *id.* at 429 (the punitive damage award "was an irrational and arbitrary deprivation of the property of the defendant"). This award is entirely arbitrary and illogical. There is simply no relationship between worldwide sales of an FDA-approved prescription drug and an alleged adverse reaction to that drug by a particular person. Nor is there any relationship between the time period for such sales referenced by plaintiff's counsel during her summation – the five weeks during which Mr. Wakefield took Rezulin – and any rational basis for a punitive damage award. By the same reasoning, if the worldwide sales of Rezulin during some particular

period were greater, so that even more diabetics would have benefitted from the medication, then the punitive damages would *increase*. This makes no sense, and is unconstitutionally arbitrary.

Denial of Due Process because of a lack of evidence of the amount of "financial benefit" to defendants in Oklahoma, nationwide or internationally, during the five-week period. The record contains evidence only (1) from annual reports, of the worldwide sales of Rezulin in a calendar year, and (2) from a document prepared in advance of any Rezulin sales, that Warner-Lambert intended to "strive" for a 30% profit on Rezulin. R.3806, Tr. 2090. There is nothing in the record to support the Court of Civil Appeals' statement (without citation) that there was "expert testimony" establishing a 30% profit margin on Rezulin (App. 17), and no evidence of the actual profit margin for Rezulin while it was on the market. Thus, the evidence cannot provide a basis for a finding of "financial benefit" from Rezulin sales, whatever the scope of sales considered, and certainly not in relation to a specific five-week period or within Oklahoma. Plaintiff did not even show the amount of Rezulin sales in Oklahoma, during any period. It is a due process violation to enter a judgment against a party when there is no evidence to support the judgment. *See Thompson v. City of Louisville*, 362 U.S. 199, 206 (1960) (and cases cited in n.13 thereof).

Far-reaching health care policy implications of the decision below. Both *BMW* and *State Farm* expressed concern with the implications of excessive or arbitrary punitive damages awards. Here, the potential consequences to both the parties and the public overwhelm those cited in those two cases. The overriding fact is that the FDA approved Rezulin for nationwide sale. A huge

state court punitive damage award regarding an FDA-approved prescription drug, based on worldwide sales, and contrary to this Court's requirements, undermines the FDA's expert, authoritative determination that – balancing the potential for harm to some patients against the benefits to many – the drug should be approved for sale and should remain on the market. *See BMW*, 517 U.S. at 571 (only Congress has authority "to enact such a policy for the entire nation").

As this Court has recognized, punitive damages have a "devastating potential for harm." *State Farm*, 538 U.S. at 417. The potential for punitive damages based on FDA-approved worldwide sales, faced by any pharmaceutical manufacturer whose product, like all prescription drugs, has risks as well as benefits, is daunting. In pharmaceutical product liability cases such as this, the potential devastating harm is that punitive damage awards will chill the incentive for research and development and diminish the availability of vitally needed new medications for life-threatening diseases, such as diabetes, with severe adverse consequences for public health. *See* Note, "A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals," 103 *Harv. L. Rev.* 773, 774-75 (1990) ("[T]he tort system undermines the availability of pharmaceuticals. Even in the absence of liability judgments, the mere fear of astronomical liability may render a drug uninsurable and consequently unmarketable. In the event a beneficial drug does reach the market . . . litigation costs alone may force the manufacturer to withdraw its product" or "have marked effects on pricing and production.").

Because of the potential for juries to undermine governmental regulation through punitive damage awards,

numerous courts have held that governmental approval or compliance with federal regulations precludes punitive damages.[7] Thus, while FDA approval of a prescription drug and its labeling may not insulate the manufacturer from liability in an individual personal injury action, it should at least preclude a finding that, by selling the drug, the manufacturer was engaged in "illegal" conduct or acted with the malice, recklessness, or wanton disregard for public safety required for punitive damages.

In the circumstances of this case, and many other prescription drug personal injury actions, allowing punitive damages to be calculated from nationwide sales, including sales to those for whom the drug was effective and caused no ill effects, would allow one jury in one case to undermine the regulatory determination made by the FDA, after examining the scientific debate, that the benefits of a drug outweigh the risks. That is the same

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[7] This was a ground for denial of punitive damages argued to the trial court (R.3829, at 14-16) and incorporated into defendants' appellate brief at 29. *See, e.g., Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994), *cert. denied*, 513 U.S. 1111 (1995) (compliance with federal vehicle safety standards precludes a finding of "wantonness"); *Ralph Nader Conn. Citizen Action Group v. Allegheny Airlines, Inc.*, 626 F.2d 1031, 1035 (D.C. Cir. 1980) ("An airline may not be condemned as a wanton wrongdoer for conforming to the standards set and the practices approved by the agency charged with the duty of regulating it"); *Harrison v. Indiana Auto. Shredders Co.*, 528 F.2d 1107, 1124-26 (7th Cir. 1975) (punitive damages reversed where defendant had zoning authority and a permit, and acted on expert advice); *In re Miamisburg Train Derailment Lit.*, 725 N.E.2d 738, 752 (Ohio Ct. App. 1999) (compliance with federal regulation "overwhelm[s] any suggestion that appellees acted with conscious disregard for safety"; affirming summary judgment); *Chrysler Corp. v. Wolmer*, 499 So. 2d 823, 826 (Fla. 1986) (compliance with federal standard for fuel system integrity negates conclusion that defendant acted with "a wanton disregard for life equivalent to manslaughter").

reasoning that has led courts to hold that punitive damages are inappropriate where experts in the scientific community disagree on scientific conclusions, which is clear from the record in this case.[8] Physicians at FDA approval hearings supported the use of Rezulin, and all of the physicians involved in this case who had prescribed Rezulin testified that in their experience the drug was safe and effective – as Mr. Wakefield's own endocrinologist put it, Rezulin was "excellent" and "really outstanding." R.3797, Tr. 1779, R.3798, Tr. 1836. Conversely, plaintiff's sole causation expert, Dr. Julie, admitted that his theory that Rezulin causes hemolytic anemia "has not been tested or confirmed." R.3795, Tr. 1651. Theories that had not been tested or published in 2002 cannot possibly be a predicate for punitive damages based on what Warner-Lambert knew or should have known in 1999.

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[8] This point also was argued to the trial court (R.3829, at 12-14) and incorporated into defendants' appellate brief at 29. *See, e.g., Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1313, 1317 (5th Cir. 1995), *cert. denied*, 516 U.S. 1045 (1996) (punitive damage award vacated because, *inter alia*, "there is a genuine dispute in the scientific community as to whether [motorcycle] leg guards do more harm than good"); *AMPAT/Midwest, Inc. v. Illinois Tool Works Inc.*, 896 F.2d 1035, 1044 (7th Cir. 1990) (affirming order setting aside punitive damages, despite "highly irresponsible behavior" by defendant, given the "disagreement between [experts] over the gravity of the defects" in screws, and about causation); *Berroyer v. Hertz*, 672 F.2d 334, 342 (3d Cir. 1982) ("difference of medical opinion" among experts provided "insufficient support" for punitive damages); *ACandS, Inc. v. Asner*, 686 A.2d 250, 265 (Md. 1996) (reversible error to submit punitive damages to jury where evidence showed "differences of opinion in the state of the art at the time" regarding product risks); *Loitz v. Remington Arms Co.*, 563 N.E.2d 397, 407 (Ill. 1990) (legal standard of " 'flagrant indifference' to public safety" was not satisfied where "expert witnesses disagreed on the safety and suitability of the material" used in shotgun barrels).

In sum, the punitive damage award was impermissibly calculated on the basis of out-of-state conduct – Warner-Lambert's worldwide sales of Rezulin – in conflict with this Court's decisions. In *State Farm*, 538 U.S. at 418, the Court stated that: "Our concerns are heightened when the decisionmaker is presented . . . with evidence that has little bearing as to the amount of punitive damages that should be awarded." In this case, the ***only*** evidence that plaintiff's counsel told the jury it should consider on the amount of punitive damages had ***no*** constitutionally permissible bearing on that determination.

II. THE PUNITIVE DAMAGE AWARD IS UNCONSTITUTIONALLY EXCESSIVE

The amount of the $10 million punitive damage award (nearly seven-fold the compensatory award) conflicts with the teachings of *State Farm*. There, the Supreme Court reiterated that "an award of more than four times the amount of compensatory damages might be close to the line of constitutional impropriety," and stated that where (as here) "compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *State Farm*, 538 U.S. at 425.

That is exactly the case here. Even assuming *arguendo* that there were some valid basis for punitive damages in the record, there is no basis to exceed the limits on the amount that the Court identified in *State Farm*. As discussed above, this case involves the administration of a widely successful, FDA-approved, lawfully sold prescription drug to a single patient. The risks and benefits of Rezulin are, at the very least, a matter of

legitimate scientific disagreement. Indeed, there was no disagreement on that issue among Mr. Wakefield's own treating physicians, each of whom maintained that it was safe and effective, and none of whom identified it as the cause of Mr. Wakefield's death. As in *State Farm*, 538 U.S. at 427, because there is no evidence "demonstrating harm to the people of [Oklahoma] (other than those directly involved in this case), [this] indicates that the adverse effect on the State's general population was in fact minor."

Under these circumstances, the amount of the award is vastly out of proportion to constitutional requirements and constitutes inappropriate state regulation of an FDA-approved prescription drug on a national basis, further implicating concerns about chilling the incentive for development of pioneering new prescription drugs. *See BMW*, 517 U.S. at 585 (no State "may use the punitive damages deterrent as a means of imposing its regulatory policies on the entire Nation"). The petition should therefore be granted for this reason, as well.

CONCLUSION

The Court should grant the petition for certiorari, summarily reverse, or remand for consideration in light of the requirements of *State Farm* and *BMW*.

Respectfully submitted,

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IN THE COURT OF CIVIL APPEALS
STATE OF OKLAHOMA
DIVISION IV

MARY ROSE WAKEFIELD, individually, and as Personal Representative, Trustee, and Executor of the Estate of Michael Holmes Wakefield, Plaintiff/Appellee, vs. WARNER-LAMBERT COMPANY; PARKE-DAVIS DIVISION OF WARNER-LAMBERT COMPANY, and PFIZER, INC., Defendants/Appellants, and SIMON LEVIT, M.D., and his professional corporation, professional association, unincorporated association, or other business entity, Defendants.	Case No. 99,086 Not For Official Publication (Filed Jul. 20, 2004)

APPEAL FROM THE DISTRICT COURT OF
TULSA COUNTY, OKLAHOMA

HONORABLE SHARRON BUBENIK, TRIAL JUDGE

AFFIRMED

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OPINION BY RONALD J. STUBBLEFIELD, JUDGE:

This is an appeal by defendant drug manufacturers from judgment on jury verdict in a wrongful death product liability action. Based on our review of the record on appeal and applicable law, we affirm.

FACTS AND PROCEDURAL HISTORY

In early 1999, forty-one year old Michael Holmes Wakefield, a sufferer of adult-onset (Type II) diabetes, began taking the prescription drug Rezulin (troglitazone), prescribed by his physician, Dr. Simon Levit, for treatment of the disease. He took the drug for approximately one month and then on March 8, 1999, he presented at the hospital emergency room with symptoms of nausea, vomiting, diarrhea and jaundice. He was admitted to the hospital. Initial tests indicated liver failure, and within the next week Wakefield's (hereafter referred to as Decedent) condition catastrophically deteriorated, and he died on March 15, 1999.

In October 2000, this cause of action was filed by Decedent's wife, Mary Rose Wakefield, acting in various

capacities, and his mother, Mary Louise Wakefield.[1] Plaintiff sued Dr. Levit, claiming he was negligent, and also sued the entities that we shall refer to as the Manufacturing Defendants – Warner-Lambert Company and its Parke-Davis Division (hereafter referred to as WLC), and also Pfizer, Inc., based on the allegation that it was the successor-in-interest of WLC. The claims against the Manufacturing Defendants were that they knew of the highly toxic nature of Rezulin, *had actually downplayed and understated the dangers of the drug in order to obtain approval of the drug by the regulatory Food and Drug Administration (FDA),* and failed to adequately warn physicians and the public of the very high risk of liver damage from use of the drug.

The pretrial litigation was intensive and the case finally went to trial against the Manufacturing Defendants[2] in March 2002. After a three and one-half week trial, with innumerable witnesses and thousands of pages of exhibits, the jury returned two verdicts against the Manufacturing Defendants awarding compensatory damages of $1,550,000 and punitive damages of $10,000,000. The Manufacturing Defendants appeal.

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[1] Defendants filed a motion to dismiss the wrongful death claim of Decedent's mother, Mary Louise Wakefield. However, the disposition of that motion is not apparent from review of the record. In any event, the case proceeded to trial with only the wife, Mary Rose Wakefield, as plaintiff. Thus, hereafter, discussion shall refer only to the singular term "Plaintiff."

[2] The trial was directed solely to liability of the Manufacturing Defendants, and not Dr. Levit. The appealed judgment is solely against "Warner-Lambert, Company, now Pfizer, Inc.," and Dr. Levit is not a party to this appeal.

DISCUSSION OF ISSUES[3]

I. Jury Instruction Issues

The first contention of error is that the Trial Court erred in refusing to give two instructions proffered by Manufacturing Defendants – a condition-versus-cause instruction and a "comment k" instruction regarding unavoidably unsafe products. In reviewing jury instructions on appeal, this Court must consider the instructions as a whole. *Dutsch v. Sea Ray Boats, Inc.,* 1992 OK 155, ¶ 7, 845 P.2d 187, 189. The instructions need not be ideal but must reflect Oklahoma law regarding the subject at issue. *Id.* The salient test for error in instructions is whether the jurors were probably misled regarding the legal standards they should apply to the evidence. *King v. Neal,* 2001 OK CIV APP 11, ¶ 11, 19 P.3d 899, 902. "Before the court will reverse a judgment based on the verdict of a jury because of the giving or refusal to give instructions, it must clearly appear that the instructions given or refused have caused a miscarriage of justice." *Larkins-Warr Trust v. Watchorn Petroleum Co.,* 1946 OK 84, ¶ 0, 174 P.2d 589 (syllabus 2).

A. Condition Versus Cause

The condition-versus-cause argument is based on the defense by Manufacturing Defendants that the actual cause of death of Decedent was not injury from Rezulin but injury resulting from administration of another drug

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[3] Manufacturing Defendants raised fifty propositions of error in their petition in error, but we address only those issues briefed and deem the remaining issues waived. *Hadnot v. Shaw,* 1992 OK 21, ¶ 7, 826 P.2d 978, 981.

to Decedent prior to his death, Rocephin. The instruction offered by Defendants states:

> There is a difference between a direct cause and a condition. If the defendant's act or omission merely creats [*sic*] a condition by which the injury was made possible, and a subsequent independent act caused the injury, the existence of that condition is not the direct cause of the injury. If you find that Rezulin created a condition, but that Rocephin was the direct cause of Mr. Wakefield's death, then you must return a verdict in favor of the Defendants.

Manufacturing Defendants cite *Thur v. Dunkley,* 1970 OK 157, 474 P.2d 403, as authority for this instruction. However, that was a case of clear *intervening* negligence, where a driver had stopped to fix a flat tire, two other cars stopped behind him, and a fourth vehicle then collided with the rear car propelling it into the other stopped automobile. The Oklahoma Supreme Court concluded it was the negligence of the fourth driver that caused the accident, and not the act of the first driver in stopping to fix his tire. The Court spoke of a "series of unfortunate events . . . caused by the intervening negligence" of another party. *Id.* at ¶ 22, 474 P.2d at 406.

In this instance there was no allegation or evidence of true intervening negligence. Plaintiff claimed that Rezulin caused severe damage to Decedent's liver, which led to his death. Manufacturing Defendants claimed that Decedent suffered another medical condition after his hospitalization which caused his death, hemolysis (also called hemolytic anemia), which is defined as the destruction of red blood cells that leads to the release of hemoglobin from within the red blood cells into the blood plasma. *Webster's*

New World Medical Dictionary (2d ed. 2003). However, the testimony of Plaintiff's expert witness, Dr. Neil Julie, was to the effect that a healthy liver would have been able to process and eliminate the excess hemoglobin, but that Decedent's Rezulin-damaged liver could not, leading to his death.

We view this dispute as simply an evidentiary dispute over proximate causation, and not a condition-versus-cause dispute. It was presented to the jury in that posture from the first words of opening statements to the conclusion of the exhaustive trial. However, even if we viewed the administration of Rocephin as a possible intervening cause, we conclude that Manufacturing Defendants' proposed instruction was an incorrect statement of law. As this Court stated in *Conatzer v. American Mercury Insurance Co.*, 2000 OK CIV APP 141, ¶ 20, 15 P.3d 1252, 1257, "not every intervening cause insulates the original negligent actor from liability. . . . When a cause combines with another act or omission to produce an injury or several causes operate to bring about the same result, each negligent actor may be liable for the harm that evolves." Instructions 9 and 10 given by the Trial Court correctly advised the jury regarding intervening causes and, therefore, we conclude that the jury was properly instructed in regard to causation issues. Accordingly, we find that the Trial Court did not err in refusing to give Manufacturing Defendants' proposed condition-versus-cause instruction.

B. The "Comment k" Instruction

Defendants also claim reversible error in the Trial Court's refusal to give an instruction based on Restatement

(Second) of Torts § 402 A, cmt. k (1965). Comment k reads as follows:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable

> product, attended with a known but apparently reasonable risk.

The Oklahoma Supreme Court has acknowledged the possible applicability of a comment k instruction. *Tansy v. Dacomed Corp.,* 1994 OK 146, 890 P.2d 881. However, the Court specifically stated:

> Comment k serves as an affirmative defense when the product is incapable of being made safe under present technology, but the social need for the product warrants its production. . . . There must be at the time of manufacture and distribution "no feasible alternative design which on balance accomplished the subject product's purpose with a lesser risk.". . . .
>
> The defense is available only when the product is properly manufactured and contains adequate warnings. . . . The comment k defense does not apply when the product is defective due to faulty manufacturing or inadequate warnings. . . .

Id. at ¶¶ 13-14, 890 P.2d at 885-86 (citations and footnotes omitted).

In *Hill v. Searle Laboratories,* 884 F.2d 1064 (8th Cir. 1989), a case cited in *Tansy,* the federal court stated:

> The drafters of comment k did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability. Such an exception was proposed at the American Law Institute meeting where section 402 A and comment k were adopted, but this proposal was defeated. . . . The language of comment k suggests that only exceptional products, albeit such exceptional products are more likely to be found in the field

> of prescription drug products, should be excluded from the strict liability provisions. But more importantly, the example given – the vaccine for the Pasteur treatment of rabies – suggests that only special products, those with exceptional social need, fall within the gamut of comment k.

Id. at 1069 (citation omitted).

Thus, to warrant a comment k instruction, Manufacturing Defendants had the burden of coming forward with evidence establishing that Rezulin was a drug for which there was an exceptional social need, and that it was incapable of being made safe under present technology. In addition, they had the burden of controverting the prima facie case Plaintiff made that the product was defective due to inadequate warnings.[4] We conclude they did neither.

The refusal of the comment k instruction was not an issue the Trial Court took lightly. The Trial Court's comments reflect a studied view of applicable law in regard to application to the facts of this case. When the request for a comment k instruction was made, the Trial Court stated:

> THE COURT: Okay. And, in fact, the Court did tell you last night that I would probably give it but I wanted to go home and, in a quiet closet, read some of the law. And I do think it was a close call, however based upon the comments made in *Hill v. Searle Laboratories,* I came to the conclusion that since it said that this particular Comment k should only apply upon a showing of exceptional social need and the committee had

[4] Discussed, hereafter, in some detail.

> considered applying this rule to all drugs and it was defeated. And even more important that the example they gave was the vaccine for Pasteur treatment of rabies. . . . [T]he federal court says that the suggested special products, those with exceptional social need, fall within the gamut of Comment k. . . . [W]e had some testimony about [Rezulin's] importance to a certain group of diabetics, I don't think it met that level.

From our review of the voluminous record, we simply do not find it clearly appears that the comment k instruction should have been given. There was testimony of doctors that the drug Rezulin worked well for some patients but Manufacturing Defendants' evidence neither addressed the issue of overall product necessity, nor controverted the substantial showing by Plaintiff that Manufacturing Defendants did not reveal substantial damning evidence they had about the drug.

Adequacy of the warnings given by Manufacturing Defendants was the critical issue in this case. Plaintiff presented the expert testimony of Dr. John Gueriguian, a medical doctor, former professor of pharmacology and former FDA medical officer. Dr. Gueriguian testified that he worked on the approvals of more than 100 drugs, including every diabetic medication on the market in America before 1996, and that he was the FDA medical officer actually assigned to Rezulin. His testimony fairly conclusively demonstrated that Manufacturing Defendants did not give adequate warnings, and even supported a conclusion that they manipulated or hid some facts that

might have prevented FDA approval of the drug.[5] Dr. Gueriguian's testimony was not effectively rebutted.

Because we find Manufacturing Defendants did not conclusively establish that Rezulin was demonstrated to be a drug of "exceptional social need," and did not controvert Plaintiff's proof that adequate warnings regarding the drug were not given, we conclude it was not error for the Trial Court to refuse a comment k instruction.

II. The Challenge to the Testimony of Dr. Julie

Manufacturing Defendants next complain that the Trial Court abrogated its "gatekeeper" duty by allowing the testimony of Plaintiff's expert witness, Dr. Neil Julie. We find this challenge to admission of evidence absolutely without merit.

Defendants made several pretrial challenges to Plaintiff's evidence, including the expected testimony of Dr. Julie. The record reflects that the evidentiary issues were subject to considerable scrutiny and that the Trial Court made specific inquiry regarding the qualifications and methodology of Dr. Julie. Clearly, Dr. Julie was highly qualified, as (1) a board-certified internal medicine physician and gastroenterologist who had dealt with several liver disorders; (2) a physician who diagnosed and treated at least three patients with Rezulin-induced liver damage that was reported in journals; and (3) a consultant and clinical researcher who had tested pharmaceutical drugs for gastrointestinal disorders. We agree with Plaintiff's

[5] Once many of these facts came to light, along with other developing evidence regarding the dangers of Rezulin, the drug was removed from the market.

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statement that the witness, because of his expertise, experience and training, was uniquely qualified to give a causation opinion regarding liver injuries.

As for Dr. Julie's methodology used in making the determination that Rezulin caused Decedent's liver injury, which included (1) review of Decedent's medical history; (2) examination of the timing of the injury; (3) creation of a differential diagnosis; and (4) exclusion of other possible causes of Decedent's injury based on experience and review of medical literature, it would pass muster in any court in this land. His methodology, particularly the scope of his inquiry and information gathering, seems to have been superior to that of other testifying expert witnesses, including the witnesses of Manufacturing Defendants. We find no merit to this contention of error.[6]

III. Evidence of WLC's Guilty Plea

Manufacturing Defendants next claim it was reversible error for the Trial Court to allow evidence, for purposes of impeachment, of a 1995 criminal conviction of WLC for falsifying information to the FDA.[7] Manufacturing Defendants argue that the basis of the conviction is unrelated to the facts of this case, and that evidence of a criminal conviction should have been allowed only if the actual company witnesses involved in this case had also been

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[6] On July 14, 2004, Manufacturing Defendants filed a "Notice of Recently Decided Authority." We remain unconvinced that admission of Dr. Julie's testimony constituted an abuse of the Trial Court's discretion.

[7] We reject Plaintiff's claim that the allegation of error was not preserved. The testimony regarding the criminal conviction is in the record.

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involved in the activities which resulted in the criminal conviction.

Title 12 O.S.2001 § 2609 permits use of evidence of a criminal conviction for purpose of attacking the credibility of a witness. The issue is whether the statute should apply to witnesses who are employees of a corporation that has been convicted of a crime. Manufacturing Defendants argue it should not or, at most, evidence of a criminal conviction should only be allowed if a testifying corporate witness is shown to have been directly involved in the activities that led to the corporation's conviction.[8] We tend to agree with Plaintiff's argument that such a limitation upon the rule would actually provide a legal advantage to a corporation which has considerable control over the representatives it involves in any particular lawsuit.[9]

Under the law, corporations generally are recognized as individuals or natural persons. 18 C.J.S. *Corporations* § 2 (1990). However, because a corporation may only act (and testify) through its employees and agents, a blanket denial of application of section 2609 to corporate employees would result in corporations having a legal advantage not available to natural persons. Thus, we conclude that there should be some applicability of the evidentiary law

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[8] Defendants cite *Walden v. Georgia-Pacific Corp.*, 126 F.3d 506 (3rd Cir. 1997), *cert. denied*, 523 U.S. 1074, 118 S. Ct. 1516 (1998), as directly on point. However, the holding of that case generally has not been followed by other courts addressing the issue, and the case did not deal with use of a conviction to impeach specific representations of honesty, trustworthiness, or good character.

[9] A good example of this is WLC's designation in this case of Dr. Daniel Krajewski as its witness about the criminal conviction, although he testified he had no personal knowledge of the facts underlying the conviction.

to corporate representatives. We find that section 2609 should be applicable in the situation where corporate representatives place the company's credibility or reputation for honesty and trustworthiness at issue. Simply put, a criminal conviction of the corporation should be admissible in evidence in regard to credibility of the representatives.

In this instance, the Trial Court instructed the jury that the credibility of witnesses was the only basis for consideration of the evidence of the criminal conviction. We find this was not error.

IV. The Punitive Damages Award

The Manufacturing Defendants next claim the judgment for punitive damages, entered on jury verdict, should be reversed or remitted. They claim the award of ten million dollars is contrary to statutory and constitutional limitations.

The jury was correctly instructed according to the strict terms of 23 O.S. Supp. 2003 § 9.1[10] which, in pertinent part, provides:

> A. In an action for the breach of an obligation not arising from contract, the jury, in addition to actual damages, may, subject to the provisions and limitations in subsections B, C and D of this section, award punitive damages for the sake of example and by way of punishing the defendant based upon the following factors:

[10] The Trial Court instructed according to OUJI-Civil 5.9, which anticipated legislative changes *to the format of* section 9.1 by amendment effective after the date of the trial.

1. The seriousness of the hazard to the public arising from the defendant's misconduct;

2. The profitability of the misconduct to the defendant;

3. The duration of the misconduct and any concealment of it;

4. The degree of the defendant's awareness of the hazard and of its excessiveness;

5. The attitude and conduct of the defendant upon discovery of the misconduct or hazard;

6. In the case of a defendant which is a corporation or other entity, the number and level of employees involved in causing or concealing the misconduct; and

7. The financial condition of the defendant.

B. Category I. Where the jury finds by clear and convincing evidence that:

1. The defendant has been guilty of reckless disregard for the rights of others; or

. . . .

the jury, in a separate proceeding conducted after the jury has made such finding, and awarded actual damages, may award punitive damages in an amount not to exceed the greater of:

a. One Hundred Thousand Dol-

a. One Hundred Thousand Dollars ($100,000.00), or

b. the amount of the actual damages awarded.

. . . .

C. Category II. Where the jury finds by clear and convincing evidence that:

1. The defendant has acted intentionally and with malice towards others; or

. . . .

the jury, in a separate proceeding conducted after the jury has made such finding and awarded actual damages, may award punitive damages in an amount not to exceed the greatest of:

a. Five Hundred Thousand Dollars ($500,000.00),

b. twice the amount of actual damages awarded, or

c. the increased financial benefit derived by the defendant or insurer as a direct result of the conduct causing the injury to the plaintiff and other persons or entities.

Manufacturing Defendants claim the ten million dollar punitive damage award indicates the jury must have used the "increased financial benefit" provision, but that there was no basis in the evidence for such an award. We disagree.

Manufacturing Defendants admit there was evidence

Manufacturing Defendants admit there was evidence of the dollar amount of world-wide gross sales of Rezulin – $48 million per month – but claim this did not give the jury the necessary information to determine "increased financial benefit" because the evidence did not give a basis for determination of actual profit from sales. However, there was expert testimony that WLC's profit margin on Rezulin sales was thirty percent. This testimony, along with that establishing the gross sales of the drug, clearly provided a basis for jury determination of increased financial benefit to Manufacturing Defendants. Thus, we find evidentiary support for the award of punitive damages.

Citing *State Farm Mutual Automobile Insurance Co. v. Campbell,* 538 U.S. 408, 123 S. Ct. 1513 (2003), Manufacturing Defendants claim there is insufficient nexus between the award of punitive damages and the actual harm suffered by plaintiff. They argue that the punitive damages must have been meant to further punish Defendants for the criminal conviction of which the jury was apprised. We reject this contention because the jury was specifically instructed regarding the basis for awarding punitive damages, and, absent specific proof to the contrary, it is presumed that the jury followed its instructions. *Stephens Prod. Co. v. Taylor,* 1997 OK CIV APP 70, ¶ 7, 949 P.2d 301, 302. Here, Manufacturing Defendants' argument is nothing more than conjecture about the basis for the jury's specific punitive damages award. They demonstrate no facts to overcome the presumption the jury followed its instructions and determined punitive damages accordingly.

Manufacturing Defendants also argue that the punitive damages award violates the rule of *BMW of North*

America, Inc. v. Gore, 517 U.S. 559, 116 S. Ct. 1589 (1996). The *Gore* case stands for two principles: (1) states have considerable flexibility in determining the level of punitive damages that they will allow in different classes of cases and in any particular case, and only when the award can fairly be categorized as "grossly excessive," *id.* at 568, 116 S. Ct. at 1595, in relation to these interests, does it enter the zone of arbitrariness that violates the due process clause of the Fourteenth Amendment; and (2) states may not impose economic sanctions on violators of its laws with the intent of changing tort-feasors' lawful conduct in other states. *Id.* at 572, 115 S. Ct. at 1597. Manufacturing Defendants do not specifically elucidate how the result of this case violates either of these principles, and we find it does not. The punitive damages award in this case neither reflects a grossly excessive award, nor attempts to sanction Manufacturing Defendants for conduct legal in other states. We find no merit to this contention of error.

V. Judgment Against Pfizer

Manufacturing Defendants' final argument is that there was no basis for the judgment against Pfizer because it did not develop, manufacture or distribute Rezulin. However, they admit that Pfizer "acquired" WLC in 2000. Under Oklahoma law, surviving corporations are liable for torts of merged corporations. *Investors Preferred Life Ins. Co. v. Abraham,* 375 F.2d 291, 293 (10th Cir. 1967). The demonstrated and/or admitted facts were a sufficient basis to impose liability upon Pfizer under this rule.

CONCLUSION

We find none of the contentions of error of Manufacturing Defendants availing of reversal of the judgment on jury verdict. Accordingly, the judgment must be affirmed.

AFFIRMED.

TAYLOR, P.J., and GOODMAN, J., concur.

July 20, 2004

IN THE SUPREME COURT OF THE STATE OF OKLAHOMA

Monday, November 1, 2004

THE CLERK IS DIRECTED TO ENTER THE FOLLOWING ORDERS OF THE COURT:

99,086 Mary Rose Wakefield, individually, and as Personal Representative, Trustee of the Estate of Michael Holmes Wakefield and Mary Louise Wakefield v. Warner-Lambert Company, et al.
Petition for certiorari is denied.
CONCUR: Watt, C.J., Opala, V.C.J., Lavender, Hargrave, Kauger, Edmondson, Taylor, Colbert, JJ.
NOT PARTICIPATING: Winchester, J.

* * *

UNITED STATES CONSTITUTION, FOURTEENTH AMENDMENT

Section 1. All persons born or naturalized in the United States and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

OKLAHOMA STATUTES, TITLE 23

§ 9.1. Punitive damages awards by jury

A. In an action for the breach of an obligation not arising from contract, the jury, in addition to actual damages, may, subject to the provisions and limitations in subsections B, C and D of this section, award punitive damages for the sake of example and by way of punishing the defendant based upon the following factors:

1. The seriousness of the hazard to the public arising from the defendant's misconduct;

2. The profitability of the misconduct to the defendant;

3. The duration of the misconduct and any concealment of it;

4. The degree of the defendant's awareness of the hazard and of its excessiveness;

5. The attitude and conduct of the defendant upon discovery of the misconduct or hazard;

6. In a case of a defendant which is a corporation or other entity, the number and level of employees involved in causing or concealing the misconduct; and

7. The financial condition of the defendant.

B. Category I. Where the jury finds by clear and convincing evidence that:

1. The defendant has been guilty of reckless disregard for the rights of others; or

2. An insurer has recklessly disregarded its duty to deal fairly and act in good faith with its insured; the jury, in a

separate proceeding conducted after the jury has made such finding and awarded actual damages, may award punitive damages in an amount not to exceed the greater of:

a. One Hundred Thousand Dollars ($100,000.00), or

b. the amount of the actual damages awarded.

Any award of punitive damages under this subsection awarded in any manner other than as required in this subsection shall be void and reversible error.

C. Category II. Where the jury finds by clear and convincing evidence that:

1. The defendant has acted intentionally and with malice towards others; or

2. An insurer has intentionally and with malice breached its duty to deal fairly and act in good faith with its insured;

the jury, in a separate proceeding conducted after the jury has made such finding and awarded actual damages, may award punitive damages in an amount not to exceed the greatest of:

a. Five Hundred Thousand Dollars ($500,000.00),

b. twice the amount of actual damages awarded, or

c. the increased financial benefit derived by the defendant or insurer as a direct result of the conduct causing the injury to the plaintiff and other persons or entities.

The trial court shall reduce any award for punitive damages awarded pursuant to the provisions of subparagraph c of this paragraph by the amount it finds the defendant or

insurer has previously paid as a result of all punitive damage verdicts entered in any court of this state for the same conduct by the defendant or insurer. Any award of punitive damages under this subsection awarded in any manner other than as required in this subsection shall be void and reversible error.

D. Category III. Where the jury finds by clear and convincing evidence that:

1. The defendant has acted intentionally and with malice towards others; or

2. An insurer has intentionally and with malice breached its duty to deal fairly and act in good faith with its insured; and the court finds, on the record and out of the presence of the jury, that there is evidence beyond a reasonable doubt that the defendant or insurer acted intentionally and with malice and engaged in conduct life-threatening to humans,

the jury, in a separate proceeding conducted after the jury has made such finding and awarded actual damages, may award punitive damages in any amount the jury deems appropriate, without regard to the limitations set forth in subsections B and C of this section. Any award of punitive damages under this subsection awarded in any manner other than as required in this subsection shall be void and reversible error.

E. In determining the amount, if any, of punitive damages to be awarded under either subsection B, C or D of this section, the jury shall make the award based upon the factors set forth in subsection A of this section.

F. The provisions of this section are severable, and if any part or provision thereof shall be held void, the decision of

the court shall not affect or impair any of the remaining parts or provisions thereof.

G. This section shall apply to all civil actions filed after the effective date of this act.